



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

8M

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,225	03/21/2000	Yi Wang	21 USA	5603

7590 04/02/2004

Mark Farber
Alexion Pharmaceuticals Inc
25 Science Park
Suite 360
New Haven, CT 06511

EXAMINER
SAOUD, CHRISTINE J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/528,225	WANG ET AL.
	Examiner	Art Unit
	Christine J. Saoud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
 - 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) Claim(s) 9-15 is/are allowed.
- 6) Claim(s) 1-3 and 5-8 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s), (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

DETAILED ACTION

Claims 16-18 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **with** traverse in Paper No. 11. Claims 1-15 are under examination in the instant application. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 06 January 2004 have been fully considered but they are not deemed to be persuasive.

Information Disclosure Statement

For Applicant's benefit, it is noted that no IDS has been received in the instant application.

Claim Objections

Claim 1 is objected to because of the following informalities: the claim contains the recitation of "consisting of and at least one". It would appear that the "and" should not be present in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Applicant's arguments regarding the enablement of the claimed subject matter have been persuasive. However, in light of these arguments, a new ground of rejection

Art Unit: 1647

is being made over claims 1-3 and 5-8. Applicant asserts that the reference which is being used in the rejection was published less than one year before the earliest priority date claimed by Applicant, and therefore, is not a proper prior art reference. Applicant is incorrect and is invited to review 35 U.S.C. 102(a) which is known or used by others in this country, or patented or described in a printed publication in this or a foreign country before the invention thereof by the applicant for a patent. In this case, the reference is prior art under 102(a) and can be used in a rejection under 35 U.S.C. 103(a) as follows.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramiya et al. (J. Autoimmunity. 10: 287-292, 1997) in view of Falorni et al. (Diabetologia 39: 1091-1098, 1996).

Ramiya et al. disclose the administration of insulin B chain in immunization therapy to delay/prevent diabetes onset in NOD mice. Ramiya et al. additionally teach the administration of GAD₆₅ in immunization therapy to delay the onset of diabetes. (See abstract and entire document). Therefore, Ramiya et al. teach that the individual administration of insulin B chain and a GAD peptide provide protective effects against diabetes in NOD mice, and art accepted model for human diabetes. Ramiya et al. do not teach a chimeric molecule of insulin B chain and a GAD peptide.

Falorni et al. teach the production of GAD peptide chimers in order to determine sensitivity of epitope-specific autoantibodies. Falorni et al. demonstrates that autoantibodies recognize and bind to the chimeric molecules (see Table 3). Falorni et al. do not teach administration of GAD peptides for the treatment of diabetes.

It would have been *prima facie* obvious to one of ordinary skill in the art to create a chimeric molecule of the insulin B chain and a GAD peptide for the treatment of diabetes because Ramiya et al. teach that the two individual molecules are effective for delaying the onset of diabetes and Falorni et al. teach that antibodies will recognize antigenic sites in a chimeric molecule of GAD peptides. One would be motivated to make a chimeric molecule of insulin B chain and GAD peptide because this would permit the administration of the two peptides in equimolar quantities for the treatment of diabetes in an individual. Additionally, the chimer may be more stable than the two

individual peptides alone, which would further add to the desirability of making the chimer. One would have a reasonable expectation of success in generating an immune response with the chimer because the individual molecules will generate an immune response and because Falorni et al. teach that antibodies will recognize different epitopes in a chimeric molecule of different GAD peptides. Therefore, the invention would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made, absent evidence to the contrary.

Allowable Subject Matter

Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-15 are allowed. Additionally, claims of the generic formula (insulin B-chain - insulin C peptide - GAD₆₅ peptide) would be allowable because the art does not teach or suggest the inclusion of the insulin C peptide in a chimeric molecule of insulin B chain and a GAD peptide).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 16-18 drawn to an invention nonelected with traverse in Paper No. 11. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTINE J. SAOUD
PRIMARY EXAMINER

Christine J. Saoud